Proposal Subject: Outbreaks of Shellfish Related Illness

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority and Section IV. Guidance Documents Chapter V Illness Outbreaks and Recall Guidance

Text of Proposal/ Requested Action Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:

(1) Each consumer's food history;
(2) Shellfish handling practices by the consumer and/or retailer;
(3) Whether the disease has the potential or is known to be transmitted by shellfish; and
(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses will be defined as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:

(1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
(2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

C. When the investigation outlined in Section .02 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;
(2) Notify receiving states, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
(4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest]

and no implicated product is likely to remain in the market place).

Guidance Documents Chapter V Illness Outbreaks and Recall Guidance
.01 Guidance for Investigating an Illness Outbreak and Conducting Recall

A. Requirements for the Authority

When an illness outbreak has occurred, immediate closure of the implicated growing area(s) will significantly reduce the chance of additional illnesses during the investigatory process. Immediate closure for the purposes of this Guidance Document means within twenty-four (24) hours of notification of the illness (NSSP Model Ordinance Chapter IV. @.03 A. (1)). If a preliminary investigation reveals that the growing area is not implicated, an immediate closure is not necessary. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2011). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2011).

In determining the appropriateness of harvest area closures in response to sporadic cases of *V.p.* illness, the Authority will:

(1) Define Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period.
(2) Not institute a harvest closure if more than thirty (30) days has passed since the last reported illness.

The Authority should assign an Illness Investigation/Recall Coordination Lead (the Lead) for the agency to be listed on the ISSC website as the agency contact person. The Lead will be the agency contact for the duration of the event.

During and after the immediate closure, the Authority must be in the process of investigating, evaluating and conducting increased surveillance. Immediate closures will not always result in an immediate recall of product. It is imperative that the Authority communicate with State Epidemiologists, local health officials, pertinent State agencies, industry and others as necessary to complete a thorough investigation.

Additionally, immediate closures may not be necessary if the investigation reveals that the illness outbreak was caused by a specific activity by a single entity which can be controlled through a product recall and an immediate corrective action in the processing or transport of product.

An illness outbreak investigation must include an evaluation of the health hazard presented and consideration of the following factors, including but not limited to:

1. Immediately send staff members out to perform growing area reconnaissance,
2. Review documentation of the information supporting growing area classification, review environmental sample trends, secure additional shellstock and/or water samples if necessary
3. Review toxin sample trends, sampling protocol and supporting information for Biotoxin closures, secure additional shellstock and/or water samples if necessary

4. Interview local sources regarding any anecdotal or factual information on the origin of contaminants (large passenger vessels, point and non-point sources),
5. Immediately send staff members out to interview certified dealer(s), restaurant staff members or retail establishment staff members to secure additional details regarding tagging, record keeping, refrigeration temperatures, handling practices, shipping and receiving information and where and from whom the shellfish products were purchased, name and telephone number of contact person,
6. When possible, interview harvesters in the area of concern to determine handling practices and specific harvest area(s)
7. Determine the identity of the product involved, the extent of distribution of implicated product, total amount of the suspected product, total amount in distribution chain, distribution information and proposed recall strategy.

A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:

1. When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses

2. When it has been determined that a specific process conducted by a dealer is the cause of the illnesses

A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market. It is reasonable for the Authority to conclude that a recall is not necessary when more than thirty (30) days has passed since the last reported case of illness.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected. Under these circumstances no closure of the growing waters is warranted in accordance with NSSP Model Ordinance, Chapter II. @.01 D.

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force II At the request of the submitter Proposal 13-101 was discussed in conjunction with Proposal 13-202. See Task Force II action on Proposal 13-202.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-101.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-101.